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| 09/302,239 | 04/29/99 | NELSESTUEN G | 09531/005001 |

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MARK S ELLINGER
FISH & RICHARDSON
60 SOUTH SIXTH STREET
SUITE 3300
MINNEAPOLIS MN 55402

| EXAMINER | |
|---|---|
| MOEZIE, F | |
| **ART UNIT** | **PAPER NUMBER** |
| 1653 | 12 |

**DATE MAILED:** 03/16/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/302,239 | Applicant(s) Nelsestuen |
|---|---|---|
| | Examiner F. T. Moezie | Group Art Unit 1653 |

☒ Responsive to communication(s) filed on *Oct 31, 2000 and Jan 2, 2001*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-22* is/are pending in the application.

Of the above, claim(s) *15 and 18-22* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14, 16, and 17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-22* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5 & 6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### STATUS OF CLAIMS

Claims 1-14, 16 and 17, drawn to Factor VII and VII (a) polypeptides, are pending prosecution in this Office action.

Applicant elected claims 1-14, 16 and 17, drawn to Factor VII and VII (a) without traverse, paper received January 2, 20001.

### OBJECTION - CLAIMS

Claims 1-14, 16 and 17 are objected to because they contain non-elected subject matter. Cancellation of the non-elected subject matter is suggested.

### COMPLIANCE WITH SEQUENCE LISTING REQUIREMENTS

**Note: Upon compliance with the requirements applicant must also amend the application to provide the SEQ ID NOS in THE SPECIFICATION (at least in the first occurance), in ALL EXAMPLES, TABLES AND THE CLAIMS.**

### REJECTION - 35 USC 112, FIRST AND SECOND PARAGRAPHS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant did not have the possession of Factor VII "comprising" as the expression encompasses the entire polypeptide sequence in addition to the intended segment as set forth in the specification as "a modified GLA domain" at the time the invention was made. Moreover, The nature of the amino acid being substituted does not encompass the various known amino acids having diverse properties (also not shown in the specification).

Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a definite sequence of "a modified GLA domain", does not reasonably provide enablement for a Factor VII or VIIa "comprising a modified GLA domain". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factor VII or VIIa is a protein having a vast number of amino acids in its sequence and one of skill in the art would expect that the preparation and use of the modified **protein** would call for undue experimentation. Further, the specification is not enabled for substitution of all kinds of amino acids, regardless of their structure and/or properties in the designated position in the GLA domain.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite and unclear regarding the location and the number of amino acids in the "GLA domain". The number of the amino acids and the position of the GLA domain in Factor VII or VIIa remains indefinite and unclear.

The claims are indefinite and unclear as to the nature and/or properties of the amino acids being substituted for the native amino acids.

**REJECTION - 35 USC 103 (a)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,516,640.

The reference shows the amino acid sequences of GLA regions of h-FVII is known in the art, TABLE at column 3. To make a conservative substitution at any position in the peptide is expected to result in a peptide having about the same properties as the unsubstituted peptide. One of ordinary skill in the art would be motivated to conservatively substitute (or delete) an amino acid in the chain depending, on the method of preparation, ease of obtaining the starting materials and etc.

US Patent No. 5,093,317 TABLE II IS CITED TO SHOW THE CONSERVATIVE AMINO ACID REPLACEMENTS.

**RESPONSE TO APPLICANT**

In response to the **Restriction Requirement** mailed 12/05/00, applicant elected Group I invention, claims drawn to a Factor VII or VIIa polypeptides, without traverse. Claims readable on this invention are claims 1-14, 17 and 18.

The Restriction Requirement is made Final.

In response to the **Compliance with the amino acid sequence listings**, Applicants' response filed 31 October 2000 has been considered, but not found persuasive because:

Applicant already has entered some of the SEQ ID NOS in the specification. Compliance could be made in full following the procedure adopted in the parent specification at pages 4, 10, 11, 12, 25, and Example 1, FOR EXAMPLE.(amendment received 9/4/98 in the parent application file).

Finally, where is the SEQ ID NO for Factor VII (a)? How do the amino acid sequence in factor VIIa compare with factor VII amino acid sequence?

**CONCLUSION**

No claim is allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508.

F.T. Moezie

MARY EXA
RT UNIT 18